



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2014-N-0108]

New Animal Drug Applications; Confidentiality of Data and Information in a New Animal Drug Application File; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of July 30, 2014, for the final rule that appeared in the Federal Register of March 17, 2014. The direct final rule amends the regulation regarding the confidentiality of data and information in and about new animal drug application files to change when certain approval-related information will be disclosed by the Agency. This change ensures that the Agency is able to update its list of approved new animal drug products within the statutory timeframe. It also permits more timely public disclosure of approval-related information, increasing the transparency of FDA decisionmaking in the approval of new animal drugs. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the Federal Register of March 17, 2014 (79 FR 14609) confirmed: July 30, 2014.

FOR FURTHER INFORMATION CONTACT: Scott Fontana, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0656.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 17, 2014 (79 FR 14609), FDA solicited comments concerning the direct final rule for a 75-day period ending June 2, 2014. FDA stated that the effective date of the direct final rule would be on July 30, 2014, 30 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 321, 331, 351, 352, 356a, 360b, 371, 379e, 381.

Accordingly, the amendments issued thereby are effective.

Dated: June 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-15209 Filed 06/30/2014 at 8:45 am; Publication Date: 07/01/2014]